

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

Drug Safety and Risk Management Advisory Committee (DSaRM)

**Holiday Inn Gaithersburg
Two Montgomery Village Avenue
Gaithersburg, Maryland
February 9 & 10, 2006**

DRAFT AGENDA

DAY ONE

8:00 a.m.	Call to Order and Introductions Conflict of Interest Statement	Peter Gross, M.D., Chair (DSaRM) Victoria Ferretti-Aceto, Pharm.D. Executive Secretary Drug Safety and Risk Management Advisory Committee
8:15 a.m.	Opening Remarks	Dr. Gerald Dal Pan, M.D., Director Office of Drug Safety
8:30 a.m.	Attention Deficit Hyperactivity Disorder Drugs (ADHD)-Background	Andrew Mosholder, M.D.
9:00 a.m.	Adverse Cardiovascular Events with ADHD drugs	Kate Gelperin, M.D.
9:30 a.m.	Update on Feasibility Studies (tentative)	David Graham, M.D.
10:00 a.m.	Break	
10:15 a.m.	Challenges of Cardiovascular Drug Safety Epidemiology in Post Market Drug Arena	To be announced
10:45 a.m.	Question and Answer Period	
11:30 a.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Break	
2:15 p.m.	Introduction of Questions	Gerald Dal Pan, M.D.
2:30 p.m.	Committee Discussion of Questions	
5:00 p.m.	Adjourn	

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DAY TWO

8:00 a.m.	Call to Order and Introductions Conflict of Interest Statement	Peter Gross, M.D., Chair (DSaRM) Victoria Ferretti-Aceto, Pharm.D. Executive Secretary Drug Safety and Risk Management Advisory Committee
8:15 a.m.	Open Public Hearing	
9:15 a.m.	General Office of Drug Safety Updates	Gerald Dal Pan, M.D.
10:00 a.m.	Drug Safety Oversight Board Update	Susan Cummins, M.D.
10:30 a.m.	Break	
10:45 a.m.	Risk Management Program, Status Update-NSAIDs and COX-2 Drugs	Sharon Hertz, M.D.
11:15 a.m.	Introduction-Isotretinoin risk management program	Jill Lindstrom, M.D.
11:30 a.m.	Description of iPLEDGE	To be announced
1:00 p.m.	Adjourn	